

REMARKS

Claims 1 and 19-23 were examined. Claims 1 and 19-23 are amended. Claims 24 - 42 are added. Examination and reconsideration of all pending claims are respectfully requested.

Amendment to Figures

The drawings were objected to as failing to include reference signs mentioned in the description. Submitted herewith are amended FIGS. 1-8 that include reference numerals that correspond to the reference signs used in the description. Amended FIGS. 1-8 are incorporated by reference into the present application from U.S. Application S.N. 09/300,317, filed November 25, 1998. As such, no new matter has been added thereby.

Rejection of Claims Under 35 U.S.C. § 112, second paragraph

Claims 19-23 were rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Such rejections are overcome in part and traversed in part as follows:

Claim 19 has been amended to replace "across the length of the patient's body l being treated" with --across the length of the patient's body *lumen* being treated--. Furthermore, Applicant submits that the element "the length of the patient's body lumen," does not positively claim a portion of the body, but merely defines where the thin wall graft members are positioned. Applicant has also amended claim 20 to recite that the body lumen is an artery. Similar to claim 19, claim 20 does not positively claim a portion of the body, but is merely defining the environment of where the graft is positioned.

Per the suggestion of the Examiner, Applicant has amended claim 21 to replace "the graft comprises" with --the plurality of thin wall graft members comprise--.

Claim 22 has been amended to positively recite an inner most thin wall graft member and at least one other thin wall graft member.

Claim 23 has been amended to recite a "longitudinal axis" reference frame and "a transverse dimension relative to the longitudinal axis."

The above claim amendments do not narrow the scope of the claims but merely clarify the claimed subject matter. All pending claims should now be in condition for allowance.

Rejection of Claims Under 25 U.S.C. § 102

Claims 1 and 19-22 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,354,329 to Whalen ("Whalen"). Claims 1 and 19-21 are also rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,735,897 to Buirge ("Buirge"). Claims 1 and 19-22 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,931,865 to Silverman et al. ("Silverman et al."). Such rejections are traversed in part and overcome in part as follows.

Claim 1 recites an endovascular graft for supporting a preselected length of a patient's body lumen. The graft includes a plurality of separate graft members configured to be separately layered in a deployment state in the body lumen. At least two of the graft members have a length greater than the preselected length of the patient's body lumen. Claim 19 provides a graft for treating a length of a patient's body lumen. The graft comprises a plurality of thin wall graft members. The thin wall graft members are configured to be separately layered in a deployed state in the body lumen with at least two layers of thin wall graft members present across the length of the patient's body lumen being treated.

None of the cited art describe or suggest the endovascular grafts recited by the pending claims. For example, Whalen describes vascular prostheses that comprise an interior strata, a medial strata and an exterior strata that are united in the vascular prostheses (col. 8, lines 7-9). Whalen describes that the medial and exterior strata are integral parts of the multilaminar tubular member (*see* col. 6, lines 10-14 and col. 7, lines 24-28) and the graft is manufactured so that each stratum is attached to other stratum prior to delivery into the body lumen (col. 9, lines 3-45). There is no description or

suggestion of an endovascular graft that comprises graft members that are configured to be separately layered in the body lumen, as is required by independent claims 1 and 19.

Buirge also fails to describe or suggest an endovascular graft that comprises a plurality of separate graft members that are configured to be separately layered in a deployment state in the body lumen, as is recited by claims 1 and 19.

Buirge's three layers 12, 14, 16 appear to be manufactured integral with each other prior to delivery into the body lumen. (See col. 4, lines 31-63). As such, Buirge does not describe or suggest the endovascular graft of claims 1 and 19.

Silverman describes a leak resistant tube that comprises an interference fit between inner and outer tube elements that allows for relative movement between the tube elements. However, as described on col. 8, lines 3-31, the inner and outer tube elements are each constructed over a mandrel and positioned relative to each other while outside of the body lumen. There is no description or suggestion of graft members that are configured to be separately layered in a deployment state in the body lumen.

For at least the above reasons, independent claims 1 and 19 are allowable over the cited art. For at least the same reasons, dependent claims 20-22 are also allowable over the cited art.

Rejection of Claims Under 35 U.S.C. § 103(a)

Dependent claim 23 was rejected as being unpatentable over Whalen. For at least the same reasons described above in regards to independent claim 19, dependent claim 23 should also be allowable.

Added Claims

To more fully claim the novel aspects of the present invention, Applicant has added claims 24-42. For the same reasons described above, none of the cited art describes or suggest the elements of the added claims. For example, claim 32 provides a method of deploying an endovascular graft within a body lumen. The method comprises deploying a first graft member at a section of the patient's body lumen being treated. At least one additional graft member is delivered within a longitudinal lumen of the

deployed first graft member. The at least one additional graft member is deployed within the longitudinal lumen of the deployed first graft member such that an overlapped portion of the first graft member and the at least one additional graft member span the section of the patient's body lumen being treated.

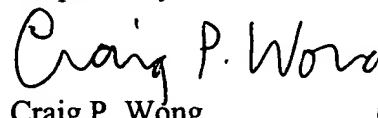
Claim 38 provides a multi-layered endovascular graft that comprises a first graft member that has a membrane and a support structure that define a lumen. One or more additional graft members that each comprise a membrane and a support structure are configured to be layered *in situ* within the lumen of the first graft member such that an overlapped portion of the first graft member and the one or more additional graft members spans a length of a compromised portion of a body lumen.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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APPENDIX A: VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) An endovascular graft for supporting a preselected length of a patient's body lumen comprising a plurality of separate **[thin wall]** graft members configured to be separately layered in a deployment state in the body lumen with at least two of the **[thin wall]** graft members having a length greater than the preselected length of the patient's body lumen.

19. (Amended) A graft for treating a length of a patient's body lumen comprising a plurality of thin wall graft members configured to be separately layered in a deployed state in the body lumen with at least two layers of thin wall graft members present across the length of the patient's body lumen being treated.

20. (Amended) The graft of claim 19 wherein the patient's body lumen that is treated is **[comprises]** an artery and none of the thin wall graft members in a **[an]** non-layered state is **[are]** sufficient to maintain a flow of blood therethrough and prevent leakage.

21. (Amended) The graft of claim 19 wherein the plurality of thin wall graft members comprise[s] at least 3 thin wall graft members.

22. (Amended) The graft of claim 19 wherein the thin wall graft members comprise an inner most thin wall graft member and at least one other thin wall graft member, wherein the **[an]** inner most thin wall graft member has an axial length greater than the other thin wall graft members of the graft and extends longitudinally beyond a distal end and proximal end of the **[all]** other thin wall graft members.

23. (Amended) The graft of claim 19 wherein the thin wall graft members comprise a longitudinal axis and are configured to expand to a transverse dimension relative to the longitudinal axis of up to about 40 mm and can be constrained to a minimum **[maximum]** transverse dimension of down to about 3 mm.

24. (Added) The graft of claim 1 wherein no single graft member has sufficient mechanical strength in the deployment state to provide a desired amount of support for the preselected length of the patient's body lumen.

25. (Added) The graft of claim 24 wherein the plurality of separate graft members comprise at least three graft members, wherein the at least three graft members are configured to provide sufficient mechanical strength to provide a desired amount of support for the preselected length of the patient's body lumen only in portions of the endovascular graft where the all the graft members are overlapped.

26. (Added) The graft of claim 1 wherein the plurality of separate graft members comprise an inner most graft member and at least one other graft member, wherein the inner most graft member has an axial length greater than the other graft members and extends longitudinally beyond a distal end and proximal end of the other graft members.

27. (Added) The graft of claim 1 wherein the plurality of separate graft members are configured to be expanded to a maximum transverse dimension of up to about 40 mm and constrained to a minimum outer transverse dimension down to about 3 mm.

28. (Added) The graft of claim 1 wherein each of the plurality of separate graft members comprise an anchoring mechanism at both ends, wherein at least two of the plurality of separate graft members have a longitudinal length sufficient to span the preselected length of the patient's body lumen and engage tissue of sufficient integrity to support the anchoring mechanisms at both ends of the at least two separate graft members.

29. (Added) The graft of claim 1 wherein at least one of the separate graft members is bifurcated.

30. (Added) The graft of claim 1 wherein at least one of the plurality of separate graft members comprises a linking means for securing the separate graft members to each other.

31. (Added) The graft of claim 1 wherein the separate graft members comprise a membrane means coupled to a frame means that supports the membrane means.

32. (Added) A method of deploying an endovascular graft within a body lumen, the method comprising:

deploying a first graft member at a section of the patient's body lumen being treated;

delivering at least one additional graft member within a longitudinal lumen of the deployed first graft member; and

deploying the at least one additional graft member within the longitudinal lumen of the deployed first graft member such that an overlapped portion of the first graft member and the at least one additional graft member span the section of the patient's body lumen being treated.

33. (Added) The method of claim 32 wherein the at least one additional graft member comprises an inner most graft member that extends longitudinally beyond a proximal end and a distal end of the first graft member and directly engages the body lumen proximally and distally of the section of the patient's body lumen being treated.

34. (Added) The method of claim 33 comprising anchoring the inner most graft into the body lumen both proximally and distally beyond the section of the patient's body lumen being treated.

35. (Added) The method of claim 32 wherein the at least one additional graft members comprises two graft members.

36. (Added) The method of claim 30 wherein at least one of the first graft member and the at least one additional graft member is bifurcated.

37. (Added) The method of claim 32 comprising percutaneously delivering the first graft member into the body lumen.

38. (Added) A multi-layered endovascular graft comprising:
a first graft member comprising a membrane and a support structure that
define a lumen;

one or more additional graft members that each comprises a membrane
and a support structure,

wherein the one or more additional graft members are configured to be
layered *in situ* within the lumen of the first graft member such that an overlapped portion
of the first graft member and the one or more additional graft members spans a length of
a compromised portion of a body lumen.

39. (Added) The endovascular graft of claim 38 wherein the first
graft member and the one or more additional graft members comprise anchoring
mechanisms on proximal and distal ends.

40. (Added) The endovascular graft of claim 38 wherein at least
one of the membrane of the first graft member and the membrane(s) of the one or more
additional graft members comprises ePTFE.

41. (Added) The endovascular graft of claim 38 wherein at least
one of the membranes of the first graft member and the membrane(s) of the one or more
additional graft members has a thickness of between approximately 0.002 inches and
0.008 inches.

42. (Added) The endovascular graft of claim 38 wherein the first
graft member is bifurcated.